Docket No.: BSX-219 (#10026334)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
YEM CHIN *et al.*

Application/Control No.: 09/963,676 Group Art Unit: 3731

Filed: September 27, 2001 Examiner: Darwin P. Erezo

For: METHOD AND APPARATUS FOR MEASURING AND CONTROLLING BLADE DEPTH OF A TISSUE CUTTING APPARATUS IN AN ENDOSCOPIC CATHETER

APPEAL BRIEF
(37 CFR § 41.37)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is filed pursuant to a July 6, 2006 Notice of Appeal and in accordance with 37 C.F.R. § 41.37. A Pre-Appeal Brief Request for Review was filed on July 6, 2006. A Notice of Panel Decision was mailed on August 18, 2006, reporting that the application "remains under appeal."

Authorization is given to charge any necessary fees to our Deposit Account No. 50-0624 fee as required under 37 C.F.R. § 41.20(b)(2) for filing this Brief, and any required petition with fee payment for extension of time.

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I. REAL PARTY IN INTEREST

The real party in interest is Scimed Life Systems, Inc., the assignee of record, which is owned entirely by Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals or interferences that are related to or will directly affect or be directly affected by or have a bearing on the Board's decision in this pending appeal.

III. STATUS OF CLAIMS

Currently pending claims 27-29, 31, 32 and 35-39 stand rejected and are on appeal. Claims 1-9, 12-20, 24, 30 and 33 have been cancelled. Claims 10, 11, 21-23, 25, 26 and 34 have been withdrawn from consideration but not cancelled. No claims have been allowed.

IV. STATUS OF AMENDMENTS

No amendment has been submitted for entry subsequent to the mailing of the February 6, 2006 Final Office Action. All prior submitted amendments have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

There are three independent claims: 27, 31, and 35. There are seven dependent claims: 28 and 29 (depend from 27); 32 (depends from 31); and 36-39 (depend from 35).

Independent method claim 27 claims a method for determining the length of a tissue cutting device that has been exposed from the distal portion of a lumen of an endoscopic catheter. This is achieved by having a plurality of radiopaque indicia located along the length of the exposed cutting device and subjecting the device to radiography. Independent method claim 31 is nearly identical to claim 27, except for the added proviso that a reference point is added.

Independent apparatus claim 35 claims a catheter device having at least one lumen wherein a tissue cutting device is disposed in said lumen, said tissue cutting device . . . disposed for extension out of . . . said lumen, and said tissue cutting device having at least one radiopaque indicia wherein the length of the tissue cutting device that has been exposed beyond the distal portion of a lumen of the catheter is the length the radiopaque indicia is moved in the lumen.

Each of independent method claims 27 and 31 recite:

> "providing said tissue cutting device with a plurality of radiopaque indicia located at radiologically measurable intervals along a length of said tissue cutting device" (Abstract; page 5, lines 3-7; and page 14, lines 1-17; Figures 10, 11 and 12, reference characters 1001-1004, 1101, 1102 and 1202-1205);
>
> "deploying said tissue cutting device to be exposed from said distal portion of said lumen" (Abstract; page 5, lines 3-7; and page 14, lines 17; Figures 10, 11 and 12, reference characters 1001-1004, 1101, 1102 and 1201-1205); and,
>
> "radiologically determining the length of said tissue cutting device as deployed from said distal portion of said lumen." (Abstract; page 5, lines 3-7; and page 14, lines 1-17; Figures 10, 11 and 12, reference characters 1001-1004, 1101, 1102 and 1201-1205).

Method independent claim 31 further recites:

> "providing a radiopaque reference point." (page 5, lines 3-14; page 10, lines 12-14, Figure 4, reference character 407; and page 14, line 25, to page 15, line 3).

Independent apparatus claim 35 covers a catheter having at least one lumen, the catheter comprising:

> "a tissue cutting device disposed in said lumen, said tissue cutting device having a cutting member disposed for extension out of an opening in said lumen" (Abstract; page 5, lines 3-17; and page 14, lines 1-14; Figures 10, 11 and 12, reference character 1201);
>
> "said tissue cutting device further disposed in said lumen for movement along said lumen to move said cutting member out of said opening" (Abstract; page 5, lines 3-17; and page 14, lines 1-14; Figures 10, 11 and 12, reference character 12010;

"at least one radiopaque indicia disposed on said cutting device to move with said tissue cutting device in said lumen" (page 5, lines 3-17; and page 14, lines 1-14; Figures 10, 11 and 12, reference characters 1001-1004, 1101, 1102 and 1201-1205); and,

"wherein the length of said cutting member is extended from said opening is a length said radiopaque indicia is moved in said lumen." (Abstract; page 5, lines 3-17; and page 14, lines 1-14; Figures 10, 11 and 12, reference characters 1001-1004, 1101,1102 and 1201-1205)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. First Ground – Banys *et al.* in view of Pacetti

Whether method claims 27, 28, and 31, and apparatus claims 35-37 and 39 are rendered obvious by U.S. Patent No. 5,425,376 (hereinafter "Banys *et al.*") in view of U.S. Patent 6,574,497 (hereinafter "Pacetti").

B. Second Ground – Banys *et al.* in view of Pacetti and Further in View of Nebergall

Whether dependent method claims 29 and 32 and dependent apparatus claim 38 are rendered obvious by Banys *et al.* in view of Pacetti, and further in view of U.S. Patent No. 4,588,399 (hereinafter "Nebergall *et al.*").

VII. ARGUMENT

A. Applicants' Invention

Independent claims 27 and 31 claim a method for determining the length of a tissue cutting device that has been exposed beyond the distal portion of a lumen of an endoscopic catheter. This is achieved by having a plurality of radiopaque indicia located along the length of the exposed cutting device. Independent claim 31 is nearly identical to claim 27, except for the added proviso that a reference point is added. See section V, *supra*.

Independent apparatus claim 35 claims a catheter device having at least one lumen wherein a tissue cutting device is disposed in said lumen, said tissue cutting device . . . disposed

for extension out of . . . said lumen, and said tissue cutting device having at least one radiopaque indicia wherein the length of the tissue cutting device that has been exposed beyond the distal portion of a lumen of the catheter is the length the radiopaque indicia is moved in the lumen.

As explained in the application, it is difficult to accurately and consistently control the length of an exposed blade when performing incisions using an endoscopic catheter. Abstract. This invention provides an apparatus and a methodology for allowing accurate positioning of incisions performed through an endoscopic catheter. 4:25-26. As explained in the specification:

> In one embodiment, the invention is an endoscopic catheter which has a distally located tissue cutting device in a lumen thereof comprising an exposed linear cutting member, the improvement for determining the amount of cutting member deployed for cutting which comprises providing the cutting member with a plurality of radiopaque indicia located at radiologically measurable intervals. In one embodiment of the invention a radiopaque reference point is included which can be used to determine the length of the deployed cutting member by reference to the indicia. The cutting member may be a needle knife where the reference point is at the distal end of the catheter or a sphincterotome where the reference point is on the catheter proximal to the cutting member of the sphincterotome. The radiopaque indicia can be referenced from the middle of the cutting member and may include markings along the length of the cutting member as a function of the distance from the middle.

5:3-14.

For example, when cutting a "sphincter of Oddi" located in the biliary tree in order to create a larger opening in order for a stone to be removed or for allowance of another device (see Figure 5 and 10:21-11:2), it is critical to know the location and the length of the exposed tissue cutting device, e.g., a cutting wire or needle knife. That is because (a) the entire length of the

exposed cutting wire or needle knife functions as a knife to incise and cauterize the tissue,[1] and (b) the goal is to minimize trauma to the tissue. (The tissue remains intact after the incision and cauterization.). As explained in the specification:

> As can be seen from the above description one of the steps in the treatment of obstructive disease is normally the practice of tissue incision which is achieved by advancing a cutting wire endoscopically to the target site. As explained above, once the catheter tip is in position, the catheter tip is bowed (FIG. 5) to expose cutting wire 113 to tissue. Diathermic current is then passed through cutting wire 113 from RF Heating Source 121 (FIG. 1) which allows the endoscopist to incise and cauterize the *tissue at the target site. Safe and effective results are only obtained through precision positioning of cutting wire 113 and control of the portion of the exposed cutting wire. Similarly, when a needle knife distally; extends from the end of a catheter, the portion of the needle knife exposed must also be accurately known and maintained throughout the cutting procedure.*

13:3-11 (emphasis supplied).

B. The Rejection

The Examiner has rejected the claims over Banys *et al.* in view of Pacetti. The Examiner alleges Banys *et al.* teaches:

> Banys teaches a method for determining a length of exposure of a tissue cutting device from a catheter/cannula by observing the tissue cutting device which is entirely made of radiopaque (col. 6, line 9), then deploying said cutting device to the tissue. The length of the exposure of the cutting device is related to the distance of which the cannula is withdrawn (col. 6, lines 3-10). Though Banys teaches the cutting device being radiopaque, he fails to teach the radiopaque material arranged as a plurality of radiopaque indicia at measurable intervals.

February 6, 2006 Final Office Action, p. 2.

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[1] A RF heating source (121) passes diathermic current through the cutting wire (113) or needle knife (Figures 10 and 11), thereby allowing the endoscopist to incise and cauterize the tissue at the target site. 13:3-11.

> However, as shown in Fig. 3, Banys indeed teaches a catheter having a lumen that is fully capable of receiving an endoscope. Furthermore, Banys teaches a needle 16 (Fig. 2) that is inserted into the catheter tube 44 (Fig. 3). Banys teaches that needle 16 includes radiopaque material to locate the needle next to the target tissue. Locating the needle next to the target tissue would displace the needle within the catheter tube, which would inherently provide a measurable displacement length that is measurable. Thus, the method of moving a radipaque needle within the catheter to locate the needle next to a tissue would inherently teach the method of using a radiopaque material for determining displacement of a cutting device (needle) from a catheter lumen.

April 17, 2006 Advisory Action, p. 2.

The Examiner alleges that Pacetti teaches:

> [A]s seen in Fig. 3 of Pacetti, it is known in the art to provide a cutting device (needle, see abstract) with a plurality of radiopaque indicia at measurable intervals (for example: 60, 62).

Id., p. 2-3. The Pacetti reference is then used to provide a teaching of using a plurality of radiopaque markers on a needle (biopsy needle, which is what Banys *et al.* teaches).

The Examiner concludes that Banys *et al.* in view of Pacetti teach:

> Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Banys to include a plurality of spaced radiopaque indicia because having said plurality of spaced radiopaque indicia would allow the practitioner to monitor the distal and proximal portion of the biopsy needle, which would provide better positional accuracy than a single radiopaque indicia (the needle). Also, the distal or proximal radiopaque indicia is fully capable of being used as a reference point, as in a leading indicia or trailing indicia. The above combination of Banys/Pacetti also teaches the arrangement of the recited device claims, as the structure is also recited in the method steps. Pacetti also discloses having more than two radiopaque indicia, as seen in Fig. 4.

February 6, 2006 Office Action, p. 3.

C. Banys *et al.* in view of Pacetti Do Not Render Obvious Apparatus Claims 35-37 and 39 or Method Claims 27, 28, or 31

1. Banys *et al.* Does Not Disclose or Suggest a "Tissue Cutting Device Disposed In Said Lumen" or "A Tissue Cutting Device . . . Disposed for Extension Out of ...Said Lumen" as Required By Claims 35-37 and 39

Independent apparatus claim 35 claims:

> "[a] catheter having at least one lumen, said catheter comprising: a tissue cutting device disposed in said lumen, said tissue cutting device having a cutting member disposed for extension out of an opening in said lumen...and at least one radiopaque indicia on said tissue cutting device to move with said tissue cutting device. . . "

Banys *et al.* does not disclose or suggest a catheter having a tissue cutting device that is disposed in a catheter lumen, said cutting device disposed for extension out of an opening of the catheter lumen.

Banys *et al.* describes a biopsy needle (16) having a closed distal end having a lateral opening (28) in the side with at least one sharp edge. Figure 2; 5:1-7. The tool also incorporates a steel cannula (44) having a sharp leading edge (56) that is advanced over the needle to cut off the tissue sample that has been maneuvered into the lateral opening of the needle. Figures 3-6; 2:40-65, 5:9-14,

Banys *et al.* thus discloses separate mechanisms that must be structurally combined at the distal end of cannula tube 44 for tissue cutting. Thus, assuming that the area inside the steel cannula (44) corresponds to the claimed endoscopic lumen, the structure that actually cuts the tissue is ***outside*** the lumen. Namely, it is the leading distal edge (56) of the steel cannula (44) that slices off the tissue when the cannula is advanced down the needle. Banys *et al.* explain:

> The physician can maneuver the distal end of needle 16, which can be radiopaque for ease of viewing, to place a sample of the tissue within opening 28 of needle 16. Cannula hub 46 is then pushed forward along locking barrel 18, to the position shown in FIG. 4, covering opening 28 and cutting a sample of the tissue off inside

needle 16._***Cannula hub 46 is then pushed forward along locking barrel 18, to the position shown in FIG. 4, covering opening 28 and cutting a sample of the tissue off inside needle 16.***

6: 8-14 (emphasis added).

Figures 1-6 reproduced below demonstrate unequivocally that the structure that actually cuts the tissue is ***outside*** of the lumen.

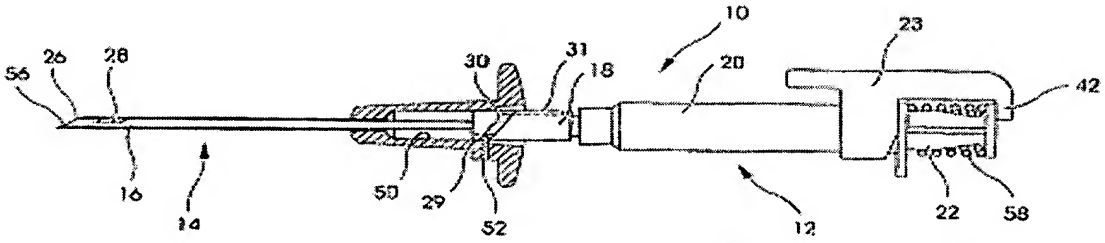

Fig. 1

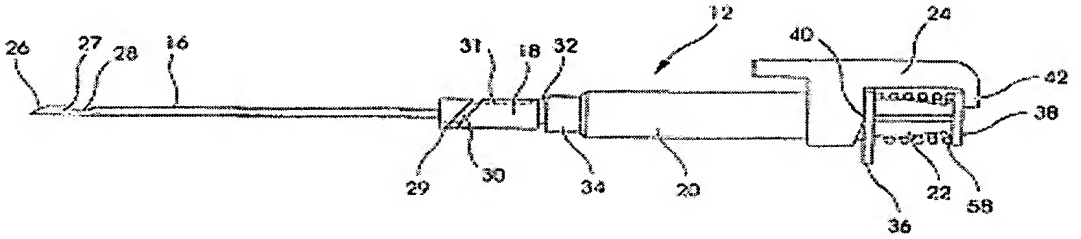

Fig. 2

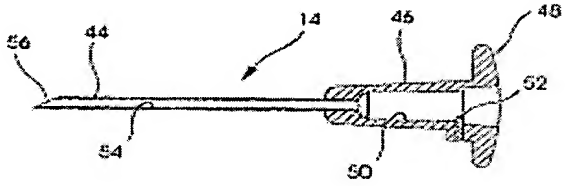

Fig. 3

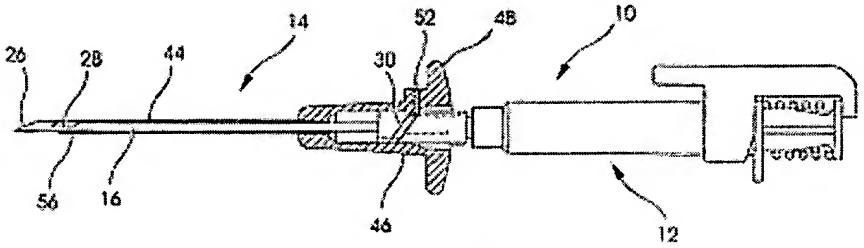

Fig. 4

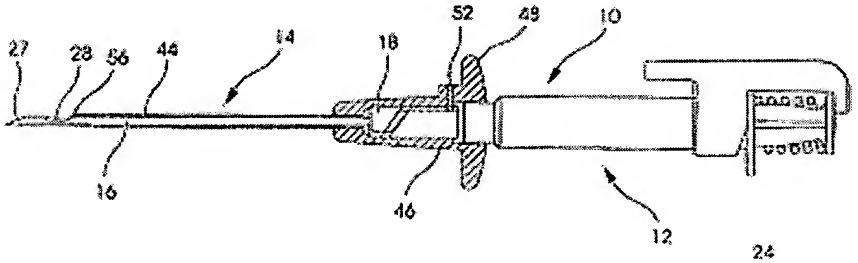

Fig. 5

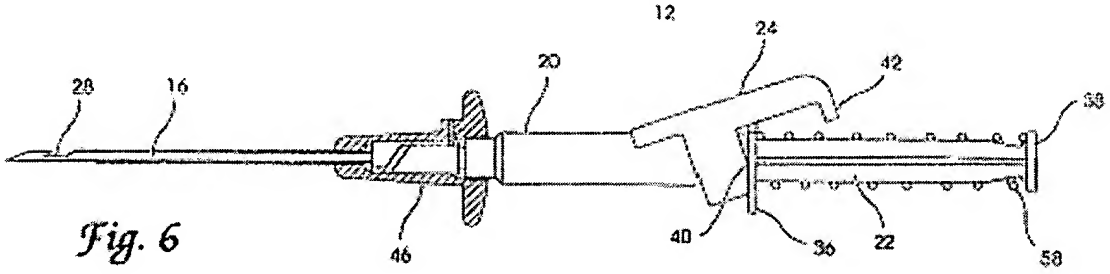

Fig. 6

Thus, Banys *et al.* teaches away from a tissue cutting device in which the tissue cutting devise is disposed *within* the lumen of the catheter.

Furthermore, Banys *et al.* does not disclose a device in which the "tissue cutting device [has] a cutting member disposed for extension *out of . . . said lumen.*" The tissue is cut only when the cannula (44) encloses the lateral opening of the needle (28), i.e., when the cannula 44 is slid over the lateral opening (28) of the needle, whereby the leading edge (56) of the cannula slices off the tissues. In other words, tissue is cut only when the lateral opening of the needle (28) is drawn into the cannula. See Figures 1-6; 1:37-39, 46-50, 57-60; 2:31-35, 53-59; 3:38-42; 5:12-14; 6:7-14. Accordingly, Banys *et al.* does not disclose or suggest a catheter having a tissue cutting device disposed for extension out of the catheter lumen.

2. Banys *et al.* Does Not Disclose or Suggest a "Method for Determining the Length Of Exposure Of A Tissue Cutting Device From A Distal Portion Of A Catheter" as Required By Method Claims 27, 28 And 31.

As previously explained, the steel cannula (44) ***is*** the structure that actually cuts the tissue. In other words, there is no cutting device which is distal to the catheter.[2] Accordingly, Banys *et al.* do not disclose or suggest a method for determining the length of exposure of a tissue cutting device from a distal portion of a catheter as required by method claims 27, 28 and 31.

Furthermore, even if the combined structure of the needle opening (28) and the sharp leading edge (56) of the cannula (44) is considered to be the tissue cutting device, there still is no distance between the sharp leading edge of the cannula and the edge of opening 28 of the needle because the leading edge of the cannula forms part of the cutting device. Thus, Banys *et al.* does

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[2] This assumes that the steel cannula (44) is considered a catheter.

not disclose or suggest a method for determining the length of exposure of a tissue cutting device from a distal portion of a catheter as required by method claims 27, 28 and 31.

Lastly, while Banys et al. does disclose the use of a radiopaque feature on the distal end of the needle, the purpose of the radiopaque feature is to align the needle with the tissue sample. It is not for determining how much of the needle is exposed outside the lumen of the cannula. Indeed, because the tissue is cut only at the lateral opening of the needle, there is no need to know where the cannula is in relation to the exposed needle. Accordingly, Banys *et al.* does not disclose or suggest method for determining the length of exposure of a tissue cutting device from a distal portion of a catheter as required by method claims 27, 28 and 31.

3. Banys *et al.* Does Not Disclose or Suggest Providing a Radiopaque Indicia On a Cutting Device Distal to the Lumen of The Endoscope Catheter as Required By Method Claims 27, 28 And 31.

Claims 27, 28 and 31 claim a method for determining the length of exposure of a tissue cutting device from a distal portion of a lumen of an endoscopic catheter by marking the length of the tissue cutting device with a plurality of radiopaque indicia and then subjecting the exposed tissue cutting device to radiation.

As explained above, the cannula (44) of Banys functions as both the endoscope catheter and the cutting device. Therefore, it is impossible for the Banys *et al.* apparatus to possess radiological indicia on a cutting device that is distal to lumen. Furthermore, even if the combined structure of the needle opening (28) and the sharp leading edge (56) of the cannula (44) is considered to be the tissue cutting device, that would not change the outcome. There still is no distance between the sharp leading edge (56) of the cannula (44) and the edge of opening 28 of the needle. Accordingly, Banys *et al.* does not disclose or suggest method for providing a

radiopaque indicia on a cutting device distal to the lumen of the endoscope catheter as required by method claims 27, 28 and 31.

The failures of Banys *et al.* to disclose or suggest the aforementioned elements of the claims stems from the fact that Banys *et al.* is directed to a fundamentally different invention than applicants' invention.

Banys *et al.* is directed to a biopsy needle in which a slidable cannula slices off tissue that is lodged in an opening of a needle. Because tissue is only cut when the leading edge of cannula (44) abuts opening (28) of the needle (16), it does not matter how much of the needle extends beyond the steel cannula.

In contrast, in applicants' invention, the cutting device extends the entire length that it is exposed beyond the endoscope.[3] Furthermore, the function of the cutting wire or needle knife is merely to incise and cauterize the tissue while minimizing trauma to the tissue. (The tissue remains intact after the incision and cauterization.) As a result, the endoscopist needs to know exactly the location of and length of the cutting device that has been extended beyond the catheter.

4. Banys *et al.* Does Not Disclose or Suggest a Cutting Device That is a Needle Knife as Required by Claim 37

Nowhere in the rejections posited by the Examiner is there a reference to Banys *et al.* disclosing or suggesting a needle knife housed within a catheter. This omission is fatal to any allegation of obviousness.

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[3] The cutting device, e.g., the cutting wire or needle knife, has a diathermic current running through it.

Banys *et al.* describe a biopsy needle exclusively. See, e.g., Figures 1-6, and Summary of the Invention 2:40-3:59; *see also* April 17, 2006 Advisory Action, p.2 ("biopsy needle, which is what Banys teaches.") A biopsy needle is not, however, a needle knife.

5. Pacetti Does Not Remedy Any Deficiencies of Banys *et al.*

The Examiner cites Pacetti for the proposition that while Banys *et al.* "teaches the cutting device as being opaque, he fails to teach the radiopaque material arranged as a plurality of radiopaque indicia at measurable intervals." February 6, 2006 Office Action, p. 2. The Examiner further argues that Pacetti provides a motivation to place multiple radiological indicia along the biopsy needle. *Id.*

Even if Pacetti provides a motivation to provide multiple radiological indicia on the needle (16) of Banys *et al,* this combination of references does not present a *prima facie* case that applicants' claims are obvious.

With respect to apparatus claims 35-37 and 39, the modified biopsy needle of Banys *et al.* would still not have a cutting device disposed within a catheter lumen, said cutting device disposed for extension out of an opening of the catheter lumen. *See sections* VII(c)(1)-(2).

With respect to method claims 27, 28, and 31, the steel cannula (44) (which allegedly corresponds to the claimed endoscopic catheter) would still be the structure that actually cuts the tissue. (Inserting radiological indicia on the needle would not change this.) Thus, the modified Banys *et al.* needle created by Banys *et al.* in view of Pacetti would still not disclose or suggest a method for determining the length of exposure of a tissue cutting device from a distal portion of a catheter as required by method claims 27, 28 and 31.

Furthermore, with respect to method claims 27, 28, and 31, even if the combined structure of the needle opening (28) and the sharp leading edge (56) of the cannula (44) is

considered to be the tissue cutting device, there still is no distance between the sharp leading edge (56) of the cannula and the edge of opening 28 of the needle because the leading edge of the cannula forms part of the cutting device. Modifying the needle to have radiological indicia would not change this fact. Accordingly, Banys *et al.* in view of Pacetti does not disclose or suggest method for determining the length of exposure of a tissue cutting device from a distal portion of a catheter as required by method claims 27, 28 and 31.

Lastly, Pacetti does not disclose or suggest a needle knife. Pacetti lists the following devices, none of which are a needle knife.

> The device may be a guidewire, guiding catheter, angioplasty catheter, stent, embolic protection device, endovascular graft, endotracheal tube, Foley catheter, Hickman catheter, Broviac catheter, cerebrospinal fluid shunt, biliary stent, stylet, biopsy needle, electrode, percutaneous or endoluminal transducer or other desired interventional medical device. It may be a temporary or permanently implanted device.

4:17-24; *see also* Abstract. Thus, Banys *et al.* in view of Pacetti cannot render obvious claim 37 which claims a needle knife.

D. Banys *et al.* In View of Pacetti *and* Further View of Nebergall *et al.* Do Not Render Obvious Dependent Method Claims 29 or 32 or Dependent Apparatus Claim 38

Dependent method claims 29 and 32 recite that there is a radiopaque reference point at the distal end of the catheter, and dependent apparatus claim 38 recites that there is a radiopaque indicia disposed on the catheter as a reference point. The February 6, 2006 Final Office Action asserts that the primary references do not teach a radiopaque reference point. Nebergell *et al.*, however, according to the Examiner render this feature obvious. The Examiner states:

> [I]t would be obvious to one of ordinary skill in the art to use a cannula having a radiopaque tip, such as the one taught by Nebergall [U.S. Patent No. 4,588,399], because in order to determine the location of the cutting device relative to the cannula, it would be necessary to use the cannula as a reference point.

> Since Banys et al teaches using fluoroscopy to monitor the needle, it would be obvious to provide a reference point that is also usable under fluoroscopy, such as a cannula with a radiopaque tip.

February 6, 2006 Office Action, p. 3.

Nebergell *et al.* does not remedy the deficiencies of Banys *et al.* or Pacetti. Combining the teachings of all of those disclosures would merely result in a biopsy needle having a marking on the steel cannula (44).

With respect to the method claims 29 and 32, the biopsy needle would still not have any distance between the sharp leading edge of the cannula (44) and the edge of lateral opening 28 of the needle because the leading edge of the cannula is the cutting device.

With respect to apparatus claim 38, the biopsy needle would still be lacking a tissue cutting device disposed *in* the lumen or a tissue cutting device disposed for extension out of an opening of the catheter lumen.

Furthermore, there would be no motivation to combine the teachings of Nebegell *et al.* with Banys *et al.* and Pacetti. The Examiner alleges that one skilled in the art would want to "determine the location of the [Banys *et al.*] cutting device relative to the cannula." February 6, 2006 Final Office Action, p.4.

The Examiner is incorrect. Because the tissue is only cut at the lateral opening (28) on the needle – not anywhere else - one skilled in the art would not be motivated to determine the area of the needle that is exposed between the lateral opening (28) and the distal end of the cannula. The distance the cannula is from the lateral opening (28) on the needle is irrelevant.

CONCLUSION

Accordingly, for all of the foregoing reasons, none of the appealed claims are rendered obvious by the prior art. Therefore, the Examiner's rejections should be reversed.

Date: November 17, 2006

Respectfully submitted,

By _____

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VIII. CLAIMS APPENDIX

A copy of claims involved in this Appeal for Application Serial No. 09/963,676 are listed below.

Claim 27 (Previously Presented): Method for determining length of exposure of a tissue cutting device from a distal portion of a lumen of an endoscope catheter, which comprises:

providing said tissue cutting device with a plurality of radiopaque indicia located at radiologically measurable intervals along a length of said tissue cutting device;

deploying said tissue cutting device to be exposed from said distal portion of said lumen; and

radiologically determining the length of said tissue cutting device as deployed from said distal portion of said lumen.

Claim 28 (Previously Presented): Method of claim 27 wherein said step of radiologically determining said length uses a radiopaque reference point.

Claim 29 (Previously Presented): Method of claim 28 wherein said tissue cutting device is a needle knife and said radiopaque reference point is at the distal end of said catheter.

Claim 31 (Previously Presented): Method for determining length of exposure of a tissue cutting device from a distal portion of a lumen of an endoscope catheter, which comprises:

providing said tissue cutting device with a plurality of radiopaque indicia located at radiologically measurable intervals along a length of said tissue cutting device, and also providing a radiopaque reference point;

deploying said tissue cutting device to be exposed from said distal portion of said lumen; and

radiologically determining the length of said tissue cutting device which is exposed from said distal portion of said lumen.

Claim 32 (Previously Presented): Method of claim 31 wherein said tissue cutting device is a needle knife and said radiopaque reference point is at the distal end of said catheter

Claim 35. (Previously Presented) A catheter having at least one lumen, said catheter comprising:

a tissue cutting device disposed in said lumen, said tissue cutting device having a cutting member disposed for extension out of an opening in said lumen;

said tissue cutting device further disposed in said lumen for movement along said lumen to move said cutting member out of said opening;

at least one radiopaque indicia disposed on said tissue cutting device to move with said tissue cutting device in said lumen,

wherein the length of said cutting member is extended from said opening is a length said radiopaque indicia is moved in said lumen.

Claim 36. (Previously Presented) The catheter according to claim 35 wherein there are at least two radiopaque indicia disposed on said tissue cutting device and said each of said radiopaque indicia is positioned at radiologically measurable intervals along a length of said tissue cutting device.

Claim 37. (Previously Presented) The catheter according to claim 35 wherein said cutting member is a needle knife.

Claim 38. (Previously Presented) The catheter according to claim 35 wherein a radiopaque indicia is disposed on said catheter as a reference point.

Claim 39. (Previously Presented) The catheter according to claim 35, wherein there are at least three radiopaque indicia disposed on said tissue cutting device and said radiopaque

indicia are disposed from a middle of said tissue cutting device at positions that are a function of distance from the middle of said tissue cutting device.

IX. EVIDENCE APPENDIX

There is no evidence pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132 or entered by or relied upon by the Examiner to be submitted.

X. RELATED PROCEEDINGS APPENDIX

There are no related proceeding identifications or copies of decisions to be provided.